

**EXHIBIT C**  
**PRELIMINARY AMENDMENT (11/12/1999)**

1103326-0502**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants : Cotton et al.  
Serial No. : 09/077,719  
Filed : June 8, 1998  
For : NOVEL FORM OF S-OMEPRAZOLE  
Examiner : J. Fan  
Group Art Unit : 1614

<b>CERTIFICATE OF TRANSMISSION</b> <b>UNDER 37 C.F.R. 1.8</b> I hereby certify that this paper is being facsimile transmitted to the U.S. Patent and Trademark Office on <u>November 12, 1999</u> at the facsimile number <u>703-308-4734</u> .	
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Assistant Commissioner for Patents  
Washington, D.C. 20231

**PRELIMINARY AMENDMENT**

Sir:

Applicants submit this Preliminary Amendment to place the claims in conformance with  
U.S. patent practice.

**Please amend the claims as follows:**

**Cancel claim 15:**

**Amend claims 2-14 and 16 as follows:**

2. (Amended) The magnesium salt of S-omeprazole trihydrate according to claim 1, wherein the compound is in a [characterized by being] highly crystalline form.

In claim 3 at line 1, after "claim 1," insert -- wherein the compound is --, and at line 2, delete "." and insert therefor -- : --.

In claim 4 at line 1, after "1-3" insert -- or 17 --.

In claim 5 at line 2, after "1-3" insert -- or 17 --; at line 5 in step b), delete "said"; and at line 9 in step f), after "the" insert -- obtained -- and delete "thus obtained".

6. (Amended) The [A] process according to claim 5, wherein the [said] organic solvent of [used in] step a) is methanol.

7. (Amended) The [A] process according to claim 5 [claims 5-6], wherein the [said] non-solvent of [used in] step c) is acetone.

8. (Amended) The [A] process according to claim 5 wherein steps a) to e) are replaced by the following single step: [; i)] converting the potassium salt of S-omeprazole into a corresponding magnesium salt of S-omeprazole by treating the [said] potassium salt with a magnesium source in water.

9. (Amended) The [A] process according to claim 5 or 8 [claims 5-8], wherein the [said] magnesium source [used in step b) of claims 5-7 or step i) of claim 8] is magnesium sulfate.

In claim 10 at line 1, delete "a" and insert therefor -- the --; at lines 1 and 2, delete "to be used in any of claims 5-9, which process comprises" and insert therefor -- of claim 5, comprising --; at line 6, after "source;" insert -- and --; and at line 7, after "the" insert -- obtained -- and delete "thus obtained".

11. (Amended) The [A] process according to claim 10, wherein the [said] organic solvent of [used in] step a) is toluene.

12. (Amended) The [A] process according to claim 10 or 11 [any of claims 10-11], wherein the [said] potassium source of [used in] step b) is methanolic potassium methoxide or methanolic potassium hydroxide.

In claim 13 at line 1, delete "Potassium" and insert therefor -- The potassium --; and after "claim 10" insert --, wherein the compound is --; and at line 2, delete "." and insert therefor -- : --.

14. (Amended) A pharmaceutical composition comprising the magnesium salt of S-omeprazole trihydrate according to any of claims 1-3 or 17 as active ingredient and [in association with] a pharmaceutically acceptable carrier [and optionally other therapeutic ingredients].

16. (Amended) A method of treating a gastric acid related condition which method comprises administering to a subject suffering from said condition a therapeutically effective amount of the magnesium salt of S-omeprazole trihydrate according to [defined in] any of claims 1-3 or 17.

**Add new claims 17 and 18:**

17. The magnesium salt of S-omeprazole trihydrate according to claim 1, wherein the compound is in a stable form.

18. The pharmaceutical composition according to claim 14 wherein the composition further comprises other therapeutic agents.

**REMARKS**

The pending claims upon entry of this Preliminary Amendment are 1-14 and 15-18. The amendments place the claims in accordance with U.S. patent practice. Support for new claim 17 is found in the specification at page 3, line 11-13. New claim 18 contains an embodiment that was deleted from claim 14. Applicants submit that no new matter has been introduced by any of the amendments or new claims.

The subject application was filed under 35 U.S.C. §371 and represents the U.S. national phase application of International Application PCT/SE98/00974, filed 5 May 1998. Therefore, unity of invention among the pending claims must be determined in accordance with PCT Rules 13.1 and 13.2 as embodied in 37 C.F.R. §1.475(a).

### CONCLUSION

Claims 1-14 and 16-18 are in condition for allowance, which action is earnestly solicited.

Any additional fees due in connection with Preliminary Amendment should be charged to Deposit Account No. 23-1703.

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Respectfully submitted,



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